IROC Radiation Therapy QA Centers: 5 Years of Support of the NCI's NCTN Clinical Trials.

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Purpose/Objective: The Imaging and Radiation Oncology Core (IROC) Cooperative has been active for the past five years supporting the National Clinical Trial Network (NCTN) and the details of that support are reported. The objective of this work is to describe the numerous activities accomplished by IROC over the past five years in support of NCI's NCTN, Division of Cancer Prevention (DCP) and Experimental Therapeutic Clinical Trial Network (ETCTN) clinical trials.

Material/Methods: IROC was made up of six QA centers (Houston, Ohio, Philadelphia-RT, Philadelphia-DI, Rhode Island, St. Louis) providing an integrated RT and DI quality control program supporting NCI's clinical trials (Figure 1).

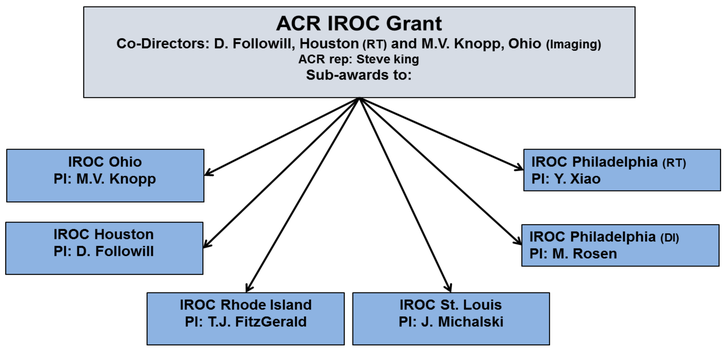
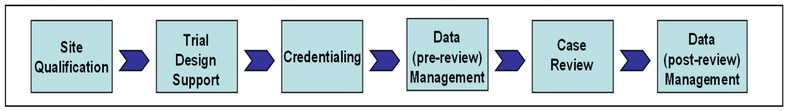


Figure 1. IROC QA Centers and their PIs.

IROC's efforts were focused on assuring high quality data for clinical trials designed to improve clinical outcomes for cancer patients worldwide. This program was administered through five core services: site qualification, trial design support, credentialing, data management, and case review.



Each QA center had specific responsibilities that minimized redundancy, relied on existing infrastructure and past trial group relations and efficient work processes. IROC QA Centers provided support to the legacy trials and new NCTN trials from the four adult and one pediatric trial groups. IROC continually interacted with the trial groups and the NCI.

Results: IROC provided core support for **198** NCTN, DCP and ETCTN trials with RT, DI and RT/DI components. All 5 groups incorporated the use of TRIAD in at least one protocol. After five years, **123 trials used TRIAD** for data submission of DICOM and DICOM RT datasets.

SITE QUALIFICATION

IROC monitored **1840** RT photon and **28** proton institutions in 32 different countries. 26 of the 28 proton centers are approved to participate in NCTN clinical trials. Over **74,000** beams outputs were monitored these past five years with ~8% of the sites requiring repeat audits due to a beam outside of the 5% criterion.

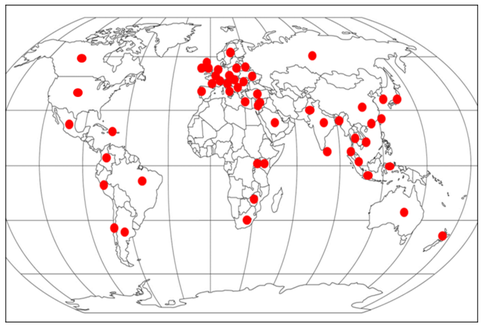
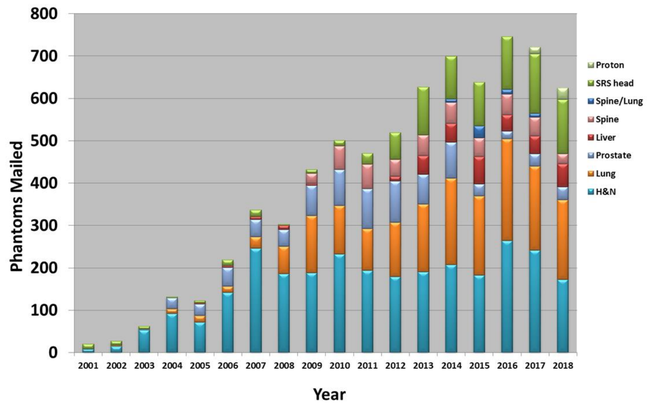


Figure 2. Countries with ≥ 1 RT centers monitored by IROC.

CREDENTIALING

As part of credentialing, **2,985** QA phantoms were irradiated, **1,600** benchmark cases were reviewed, **897** image guidance processes were assessed and **12,943** credentialing letters were issued over the past five years.



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Results:

DATA MANAGEMENT

Over the past 5 years of IROC activities, **24,368 RT** patient cases were received (many using TRIAD) by IROC and prepared for review.

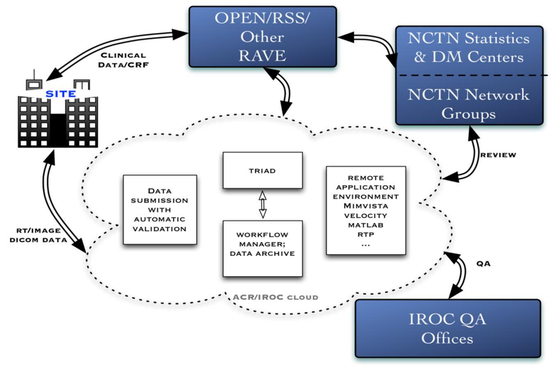

Figure 3. Patient data flow/review for NCTN clinical trials that includes TRIAD.

CASE REVIEW

Over the past 5 years, **19,881 RT** cases were reviewed by IROC technical staff for quality and interpretation. It was IROC's responsibility to prepare the data and ensure it's completeness and the NCTN Group's responsibility to interpret the cases as per protocol or deviation.

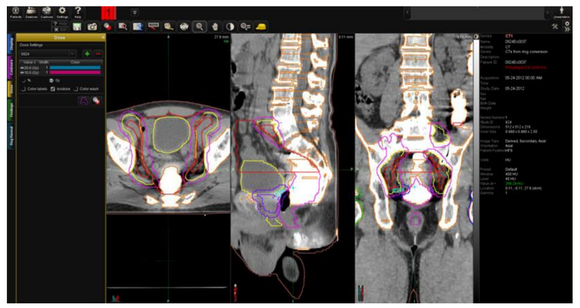

Figure 4. MiM software used for case review.

Conclusion: The volume of QA services provided by IROC were numerous, are continually being evaluated for effectiveness, harmonized across all NCTN Groups and administered in an efficient/timely manner to enhance accurate and per protocol trial data submission. To this end, **89** peer reviewed manuscripts were published supported by IROC.